



10-15-04

IFW

PTO/SB/21 (05-03)

Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

	Application Number	10/765,668	
	Filing Date	01/27/2004	
	First Named Inventor	David B. Rozema	
	Art Unit		
	Examiner Name		
Total Number of Pages in This Submission	317	Attorney Docket Number	Mirus.042.02

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application		Remarks
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Mark K. Johnson, Mirus Corporation
Signature	
Date	10/14/2004

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Kirk Ekena		
Signature		Date	10/14/2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **David B. Rozema,**)
Darren Wakefield)
)
Serial No.: **10/765,668**)
)
Filed: **01/27/2004**)
)
Group Art Unit:)

For: **Membrane Active Anions**

INFORMATIONAL STATEMENT

Commissioner of Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449. This information statement supplements the previously filed information statement.

REFERENCES CITED

- Akhtar S et al. "Interactions of antisense DNA oligonucleotide analogs with phospholipid membranes liposomes." Nucleic Acids Res; 1991 Vol. 19 no. 20 pp. 5551-9.
- Akhtar S et al. "The delivery of antisense therapeutics." Adv Drug Deliv Rev; 2000 Vol. 44 no. 1 pp. 3-21.
- Audouy S et al. "Cationic lipid-mediated transfection in vitro and in vivo." Mol Membr Biol; 2001 Vol. 18 no. 2 pp. 129-43.
- Berg T et al. "Physiological functions of endosomal proteolysis." Biochem J; 1995 Vol. 307 no. 2 pp. 313-26.

- Borszky K et al. "Enantioselective hydrogenation of α , β -unsaturated acids. Substrate-modifier interaction over cinchonidine modified Pd/Al₂O₃." *Tetrahedron Asymmetry*; 1997 Vol. 8 no. 22 pp. 3745-3753.
- Carrasco L "Entry of animal viruses and macromolecules into cells." *FEBS Lett*; 1994 Vol. 350 no. 2-3 pp. 151-4.
- Cheung CY et al. "A pH-sensitive polymer that enhances cationic lipid-mediated gene transfer." *Bioconjug Chem*; 2001 Vol. 12 no. 6 pp. 906-910.
- Danko I et al. "High expression of naked plasmid DNA in muscles of young rodents." *Hum Mol Genet*; 1997 Vol 6 no. 9 pp. 1435-1443
- Ghosh C et al. "Intracellular delivery strategies for antisense phosphorodiamidate morpholino oligomers." *Antisense Nucleic Acid Drug Dev*; 2000 Vol. 10 no. 4 pp. 263-74.
- Giles RV et al. "Antisense morpholino oligonucleotide analog induces missplicing of C-myc mRNA." *Antisense Nucleic Acid Drug Dev*; 1999 Vol. 9 no. 2 pp. 213-20.
- Heasman J et al. "Beta-catenin signaling activity dissected in the early *Xenopus* embryo: a novel antisense approach." *Dev Biol*; 2000 Vol. 222 no. 1 pp. 124-34.
- Hope MJ et al. "Cationic lipids, phosphatidylethanolamine and the intracellular delivery of polymeric, nucleic acid-based drugs." *Mol Membr Biol*; 1998 Vol. 15 no. 1 pp. 1-14.
- Kang SH et al. "Up-regulation of luciferase gene expression with antisense oligonucleotides: implications and applications in functional assay development." *Biochemistry*; 1998 Vol. 37 no. 18 pp. 6235-9.
- Kyriakides TR et al. "pH-sensitive polymers that enhance intracellular drug delivery in vivo." *J Control Release*; 2002 Vol. 78 no. 1-3 pp. 295-303.
- Lackey CA et al. "Hemolytic Activity of pH-Responsive Polymer-Streptavidin Bioconjugates." *Bioconjugate Chem*; 1999 Vol. 10 no. 3 pp. 401.
- Lackey et al. "A biomimetic pH-responsive polymer directs endosomal release and intracellular delivery of an endocytosed antibody complex." *Bioconjug Chem*. 2002 Vol. 13 No. 5 pp. 996-1001.
- Lai MZ et al. "Effects of replacement of the hydroxyl group of cholesterol and tocopherol on the thermotropic behavior of phospholipid membranes." *Biochemistry*; 1985 Vol. 24 no. 7 pp. 1646-53.
- Lai MZ et al. "Acid- and calcium-induced structural changes in phosphatidylethanolamine membrane stabilized by cholesteryl hemisuccinate." *Biochem* 1985 Vol. 25 pp. 1654-1661.
- Maeda H et al. "Mechanism of tumor-targeted delivery of macromolecular drugs, including the EPR effect in solid tumor and clinical overview of the prototype polymeric drug SMANCS." *J Control Release*; 2001 Vol. 74 pp. 47-61
- Mukherjee S et al. "Endocytosis." *Physiol Rev*; 1997 Vol. 77 no. 3 pp. 759-803.
- Murthy N et al. "The design and synthesis of polymers for eukaryotic membrane disruption." *J Control Release* 1999 Vol. 61 pp. 137-143.
- Nasevicius A et al. "Effective targeted gene 'knockdown' in zebrafish." *Nat Genet*; 2000 Vol. 26 no. 2 pp. 216-20.

- Oda T et al. "Facilitated internalization of neocarzinostatin and its lipophilic polymer conjugate, SMANCS, into cytosol in acidic pH." J Natl Cancer Inst; 1987 Vol. 79 no. 6 pp. 1205-1211
- Plank C et al. "Application of membrane-active peptides for drug and gene delivery across cellular membranes." Adv Drug Deliv Rev 1998 Vol. 34 no. 1 pp. 21-35.
- Plank C. et al. "The influence of endosome-disruptive peptides on gene transfer using synthetic virus-like gene transfer systems." J Biol Chem 1994 Vol. 269 No. 17 pp. 12918-12924.
- Robaczewska MS et al. "Inhibition of hepadnaviral replication by polyethylenimine-based intravenous delivery of antisense phosphodiester oligodeoxynucleotides to the liver." Gene Ther; 2001 Vol. 8 no. 11 pp. 874-881.
- Skehel JJ et al. "Receptor binding and membrane fusion in virus entry: the influenza hemagglutinin." Annu Rev Biochem; 2000 Vol. 69 pp. 531-69.
- Summerton J et al. "Morpholino antisense oligomers: design, preparation, and properties." Antisense Nucleic Acid Drug Dev; 1997 Vol. 7 no. 3 pp. 187-95
- Wolff JA et al. "Direct gene transfer into mouse muscle in vivo." Science 1990 Vol. 247 pp. 1465-1468
- Zuber G et al. "Towards synthetic viruses." Adv Drug Deliv Rev; 2001 Vol. 52 no. 3 pp. 245-53.

Applicant respectfully requests that these publications be expressly considered during the prosecution of this application and made of record herein and appear among the 'References Cited' on any patent to issue herefrom.

Respectfully submitted,



Mark K. Johnson Reg. No. 35,909
P.O. Box 510644
New Berlin, WI 53151-0644
(414) 821-5690

I hereby certify that this correspondence is being sent by United States Postal Service mail to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on:

10/14/04



Kirk Ekena

INFORMATION DISCLOSURE STATEMENT BY APPLICANT FORM PTO-1449	Attorney Docket No.: Mirus.42.02	Serial No.: 10/765,668
	Applicant: David B. Rozema, Darren Wakefield	Group:
		Examiner:



U.S. PATENT DOCUMENTS

Exmnr Intl	Seq	Patent Number	Issue Date	Patentee	Class	Sub Class	Filing Date

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		Document Number	Publication Date	Country or Patent Office	Class	Sub Class	Transl. yes	no

OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, etc.)

	Akhtar S et al. "Interactions of antisense DNA oligonucleotide analogs with phospholipid membranes liposomes." Nucleic Acids Res; 1991 Vol. 19 no. 20 pp. 5551-5559.
	Akhtar S et al. "The delivery of antisense therapeutics." Adv Drug Deliv Rev; 2000 Vol. 44 no. 1 pp. 3-21.
	Audouy S et al. "Cationic lipid-mediated transfection in vitro and in vivo." Mol Membr Biol; 2001 Vol. 18 no. 2 pp. 129-143.
	Berg T et al. "Physiological functions of endosomal proteolysis." Biochem J; 1995 Vol. 307 no. 2 pp. 313-326.
	Borszky K et al. "Enantioselective hydrogenation of [α],[β]-unsaturated acids. Substrate-modifier interaction over cinchonidine modified Pd/Al2O3." Tetrahedron Asymmetry; 1997 Vol. 8 no. 22 pp. 3745-3753.
	Carrasco L "Entry of animal viruses and macromolecules into cells." FEBS Lett; 1994 Vol. 350 no. 2-3 pp. 151-154.
	Cheung CY et al. "A pH-sensitive polymer that enhances cationic lipid-mediated gene transfer." Bioconjug Chem; 2001 Vol. 12 no. 6 pp. 906-910.
	Danko I et al. "High expression of naked plasmid DNA in muscles of young rodents." Hum Mol Genet; 1997 Vol 6 no. 9 pp. 1435-1443
	Ghosh C et al. "Intracellular delivery strategies for antisense phosphorodiamidate morpholino oligomers." Antisense Nucleic Acid Drug Dev; 2000 Vol. 10 no. 4 pp. 263-274.
	Giles RV et al. "Antisense morpholino oligonucleotide analog induces missplicing of C-myc mRNA." Antisense Nucleic Acid Drug Dev; 1999 Vol. 9 no. 2 pp. 213-220.
	Heasman J et al. "Beta-catenin signaling activity dissected in the early Xenopus embryo: a novel antisense approach." Dev Biol; 2000 Vol. 222 no. 1 pp. 124-34.
	Hope MJ et al. "Cationic lipids, phosphatidylethanolamine and the intracellular delivery of polymeric, nucleic acid-based drugs." Mol Membr Biol; 1998 Vol. 15 no. 1 pp. 1-14.
	Kang SH et al. "Up-regulation of luciferase gene expression with antisense oligonucleotides: implications and applications in functional assay development." Biochemistry; 1998 Vol. 37 no. 18 pp. 6235-6239.
	Kyriakides TR et al. "pH-sensitive polymers that enhance intracellular drug delivery in vivo." J Control Release; 2002 Vol. 78 no. 1-3 pp. 295-303.
	Lackey CA et al. "Hemolytic Activity of pH-Responsive Polymer-Streptavidin Bioconjugates." Bioconjugate Chem; 1999 Vol. 10 no. 3 pp. 401.
	Lackey et al. "A biomimetic pH-responsive polymer directs endosomal release and intracellular delivery of an endocytosed antibody complex." Bioconjug Chem. 2002 Vol. 13 No. 5 pp. 996-1001.



	Lai MZ et al. "Effects of replacement of the hydroxyl group of cholesterol and tocopherol on the thermotropic behavior of phospholipid membranes." Biochemistry; 1985 Vol. 24 no. 7 pp. 1646-1653.
	Lai MZ et al. "Acid- and calcium-induced structural changes in phosphatidylethanolamine membrane stabilized by cholesteryl hemisuccinate." Biochem 1985 Vol. 25 pp. 1654-1661.
	Maeda H et al. "Mechanism of tumor-targeted delivery of macromolecular drugs, including the EPR effect in solid tumor and clinical overview of the prototype polymeric drug SMANCS." J Control Release; 2001 Vol. 74 pp. 47-61
	Mukherjee S et al. "Endocytosis." Physiol Rev; 1997 Vol. 77 no. 3 pp. 759-803.
	Murthy N et al. "The design and synthesis of polymers for eukaryotic membrane disruption." J Control Release 1999 Vol. 61 pp. 137-143.
	Nasevicius A et al. "Effective targeted gene 'knockdown' in zebrafish." Nat Genet; 2000 Vol. 26 no. 2 pp. 216-220.
	Oda T et al. "Facilitated internalization of neocarzinostatin and its lipophilic polymer conjugate, SMANCS, into cytosol in acidic pH." J Natl Cancer Inst; 1987 Vol. 79 no. 6 pp. 1205-1211
	Plank C et al. "Application of membrane-active peptides for drug and gene delivery across cellular membranes." Adv Drug Deliv Rev 1998 Vol. 34 no. 1 pp. 21-35.
	Plank C. et al. "The influence of endosome-disruptive peptides on gene transfer using synthetic virus-like gene transfer systems." J Biol Chem 1994 Vol. 269 No. 17 pp. 12918-12924.
	Robaczewska MS et al. "Inhibition of hepadnaviral replication by polyethylenimine-based intravenous delivery of antisense phosphodiester oligodeoxynucleotides to the liver." Gene Ther; 2001 Vol. 8 no. 11 pp. 874-881.
	Skehel JJ et al. "Receptor binding and membrane fusion in virus entry: the influenza hemagglutinin." Annu Rev Biochem; 2000 Vol. 69 pp. 531-569.
	Summerton J et al. "Morpholino antisense oligomers: design, preparation, and properties." Antisense Nucleic Acid Drug Dev; 1997 Vol. 7 no. 3 pp. 187-195.
	Wolff JA et al. "Direct gene transfer into mouse muscle in vivo." Science 1990 Vol. 247 pp. 1465-1468.
	Zuber G et al. "Towards synthetic viruses." Adv Drug Deliv Rev; 2001 Vol. 52 no. 3 pp. 245-253.

Examiner:

Date Considered: